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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/647,720

08/25/2003

Christine Markert-Hahn

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06/13/2006

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/647,720

Applicant(s)

MARKERT-HAHN ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/27, 1/27, 11/14/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 4/28/06 to the Office action has been entered. Claims 1-15 are pending.

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-11 in the reply filed on 4/28,2006 is acknowledged. The traversal is on the ground(s) that no additional burden is placed on the Examiner to search both groups together and it is not a legitimate approach to just look at an isolated feature of a claim without giving consideration to the entire scope of the claim. This is not found persuasive because as the reasons set forth in the Office action mailed, claims 12-15 are drawn to a kit comprising bisulfite ions and a solid phase for a bisulfite reaction in which the bisulfite ion can be used as a reducing agent in cell culture to protect protein from oxidation. Thus, both groups are distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on April 28, 2006.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10540406. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-11 and claims 1-7 of copending Application No. 10540406, both are drawn to a method for the conversion of a cytosine base in a nucleic acid to an uracil base. The differences are that claims 1-7 of copending Application No. 10/540,406 require more specific temperature, the concentration of bisulfite in the solution and the pH value for deaminating a nucleic acid, while the instant claims 1-11 do not have these specific limitations except that the instant claims 1-11 require a solid phase which binds to a nucleic acid. Claims 1-7 of copending Application No. 10540406 also require a solid phase, which binds to a nucleic acid (See pg. 7, lines 5-12 of the specification). Thus the instant claims and claims 1-7 of copending Application No. 10540406 are related as genus-species. The double patenting rejection is applicable.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Information Disclosure Statement

5. The reference 59 lined through on PTO-1449 filed 11/14/03 was not considered because there is no publication date provided on this reference.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1-2 and 4-11 are vague and indefinite because of the phrase “the deaminated solid phase” in claims 1-2. It has no antecedent basis.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Olek et al. (Nucleic Acid Research, 1996, Vol. 24924, pg. 5064-5066).

Olek et al. disclose sequencing of bisulphate modified genomic DNA, which involves the method steps, recited in claim 1 for the conversion of cytosine to uracil (See pg. 5064, column 2, third paragraph, pg.5065, column 1, paragraphs 2 and 3). Thus, the teachings of Olek et al. anticipate the limitations of claim 1 that are binding the nucleic acid to a solid phase, incubating

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the solid phase bound nucleic acid in the presence of sulfite ions, incubating the deaminated nucleic acid under alkaline conditions.

10. Claims 2-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Herman et al. (5,786,146, issued July 28, 1998).

Herman et al. disclose a methylation specific PCR (See the Abstract). The method involves the step of conversion cytosine to uracil as recited in claims 2-3 (See column 11, lines 16-28). Bisulfite modification includes incubating the nucleic acid in the presence of sulfite ions, binding the deaminated nucleic acid to a solid phase, incubating the deaminated nucleic acid under alkaline conditions, eluting the deaminated nucleic acid from the solid phase and incubating the deaminated nucleic acid under alkaline conditions. Thus the teachings of Herman et al. anticipate the limitation of the claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4-11 are rejected under 35 U.S.C. 103(a) as being respectively unpatentable over Olek et al. (Nucleic Acid Research, 1996, Vol. 24924, pg. 5064-5066) or Herman et al. (5,786146, issued July 28, 1998) as applied to claims 1-3 above, and further in view of Weindel et al. (WO 01/37291, issued May 21, 2001).

The teachings of Olek et al. and Herman et al. respectively set forth in sections 9 and 10 above. Olek et al. and Herman et al. do not disclose the solid phase comprises silica or glass or glass membrane or magnetic glass particle, the magnetic particle has diameter between 0.5 and 5um, and the magnetic glass particle is manufactured by the sol-gel method.

Weindel et al. disclose the magnetic glass particle, which can be used in nucleic acid purification (See the abstract). The magnetic glass particle is a solid dispersion of small magnetic core in glass (See pg. 4, lines 9-11). The diameter of the particle is between 5 and 500nm (See pg. 4, lines 21-23 and pg. 5, lines 13-23). The magnetic glass particle is used in nucleic acid purification from a sample containing cells. The advantage of this is its potential simplicity and high sensitivity (See pg. 17, lines 1-7). Weindel et al. also disclose the method of making the magnetic glass particle by the sol-gel method and spray-drying as recited in instant claim 11 (See pg. 9, lines 13-37, pg. 21 and fig. 1). The magnetic glass particle is also used in nucleic acid amplification and hybridization assay (See pg.1).

One of ordinary skill in the art would have been motivated to apply the magnetic glass particle of Weindel et al. in the method of Olek et al. or Herman et al. as a solid support for conversing cytosine bases in nucleic acid to uracil because of the advantage of using the

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magnetic glass particle (See pg. 17, lines 1-17). It would have been prima facie obvious to apply the magnetic glass particle for the conversion of cytosine bases to uracil bases in a nucleic acid.

Summary

13. No claims are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *JT*
June 1, 2006

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

6/8/06